CLAIMS

1. Complexes of paroxetine, as free base or as salt, with a cyclodextrin or with a cyclodextrin derivative.

2. Complexes as claimed in claim 1 characterised by the form of a flowing powder, chemical stability, absence of organic solvents, high solubility in water and DSC profile different from that of the corresponding non-complexed paroxetine or paroxetine salt.

3. Complexes as claimed in claim 2 characterised by the absence of ethanol.

4. Complexes as claimed in claim 1 characterised in that they have a water content of between 1 and 20% by weight.

5. Complexes as claimed in claim 4 characterised in that said water content is between 2 and 15% by weight.

6. Complexes as claimed in claim 1, characterised in that said cyclodextrin is selected from the group consisting of α, β and γ-cyclodextrin.

7. Complexes as claimed in claim 6, characterised in that said cyclodextrin is a β-cyclodextrin.

8. Complexes as claimed in claim 1, characterised in that said cyclodextrin derivative is selected from the group consisting of eptakis (2,6-di-O-methyl)-β-cyclodextrin, eptakis (2,3,6-tri-O-methyl)-β-cyclodextrin, monosuccinyl-eptakis(2,6-di-O-methyl)-β-cyclodextrin, 2-hydroxypropyl-β-cyclodextrin, sulphated cyclodextrin and cyclodextrin containing aminoalkyl groups.

9. Complexes as claimed in claim 8, characterised in that said cyclodextrin derivative is the 2-hydroxypropyl-β-cyclodextrin.

10. Complexes as claimed in claim 1, characterised in that said salt of paroxetine is a salt with an organic or inorganic acid.

11. Complexes as claimed in claim 10, characterised in that said organic or inorganic acid is selected from the group consisting of acetic acid, maleic acid, hydrochloric acid and methanesulfonic acid.

12. Complexes as claimed in claim 11 characterised in that said acid is hydrochloric acid.

13. Complexes as claimed in claim 1, characterised in that the molar ratio between paroxetine and said cyclodextrin or cyclodextrin derivative ranges from 1:0.25 to

1:20.

14. Complexes as claimed in claim 13, characterised in that the molar ratio between paroxetine and said cyclodextrin or cyclodextrin derivative ranges from 1:0.5 to 1:2.

15. Process for the preparation of the complexes as defined in claim 1, comprising the following steps:

(a) paroxetine, as free base or as salt, a cyclodextrin or a cyclodextrin derivative and water are mixed;

(b) the obtained mixture is stirred in order to obtain an homogeneous solution or dispersion and stirring is continued until formation of the complex; and

(c) the water is partially removed in order to obtain a solid complex with the desired water content.

16. Process as claimed in claim 15 characterised in that paroxetine is used as a free base.

17. Process as claimed in claim 15 characterised in that paroxetine is used as a salt.

18. Process as claimed in claim 15 characterised in that step b) is carried out by mechanical stirring or by ultrasounds.

19. Process as claimed in claim 15 characterised in that step c) is carried out by freeze drying, drying under vacuum or under an inert gas flux.

20. Process as claimed in claim 15 characterised in that in step c) a solid complex with a water content of between 1 and 20% by weight is obtained.

21. Process as claimed in claim 20 characterised in that said water content is between 2 and 15% by weight.

22. Process as claimed in claim 16 characterised in that step a) is carried out according to the following steps:

a_1) a cyclodextrin or a cyclodextrin derivative is added to water;

a_2) the solution or dispersion of step a_1) is kept under stirring for a time from 30 to 180 minutes at a temperature between 25° and 50°C; and

a_3) paroxetine base is dispersed in the solution or dispersion of step a_2).

23. Process as claimed in claim 17, characterised in that said step a) is carried out according to the following steps:

a_1) paroxetine base is salified with an organic or inorganic acid; and

a_2) a cyclodextrin or a cyclodextrin derivative is added under stirring to the salified paroxetine.

24. Process as claimed in claim 16 characterised in that step c) is carried out according to the following steps:

c_1) the dispersion of step b) is cooled and maintained at a temperature between 4°C and 20°C for 1 to 20 hours;

c_2) the precipitate obtained in step c_1) is recovered by filtration; and

c_3) the solid product recovered in step c_2) is dried under vacuum or under an inert gas flux until the desired water content is reached.

25. Process for the preparation of complexes as claimed in claim 1 comprising slowly adding paroxetine base in the form of an oily liquid to a cyclodextrin or to a cyclodextrin derivative in a mixer for powders or in an ultrasonic mixer and continuing the stirring for a time ranging from 3 to 24 hours at a temperature from 25 to 50 °C.

26. Pharmaceutical compositions containing as an active substance a pharmaceutically effective dose of a complex as defined in claim 1, in mixture with pharmaceutically acceptable diluents or excipients.

27. Pharmaceutical compositions as claimed in claim 26 in solid or liquid form, for oral and for parenteral administration.

28. Therapeutical method for the treatment of patients suffering from depression or Parkinson's disease or other pathologies curable with paroxetine consisting of the administration of a complex as defined in claim 1, in an amount corresponding to 5-40 mg per day of paroxetine by oral way and corresponding to 1-20 mg per day of paroxetine parenterally.

add A'